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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER FLEISCHER, MARK A				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/748,730

Applicant(s)

WILSON, THOMAS W.

Examiner

MARK A. FLEISCHER

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2008.
2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 - 5, 9, 11 - 20, 23, 25 - 28 and 30 - 36 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1 - 5, 9, 11 - 20, 23, 25 - 28 and 30 - 36 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 23 July 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Status of Claims

1. This action is in reply to the Request for Continued Examination filed on 27 March 2009.
2. Claims 1 - 5, 11 - 16, 19, 20, 26 - 28 and 30 - 36 have been amended.
3. Claims 6 - 8, 10, 21, 22, 24, 37 and 38 have previously been canceled.
4. Claims 1 - 5, 9, 11 - 20, 23, 25 - 28 and 30 - 36 are currently pending and have been examined.

Continued Examination Under 37 CFR 1.114

5. A request for continued examination under 37 CFR §1.114, including the fee set forth in 37 CFR §1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR §1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR §1.114. Applicant's submission filed on 27 March 2009 has been entered.

Response to Amendments

6. The objections of Claims 1 and 34 are withdrawn in light of Applicant's amendments.
7. The rejection of claim 36 under 35 USC § 101 is maintained for reasons set forth below.

Response to Arguments

8. Applicant's arguments and amendments received on 27 March 2009 have been fully considered and while very well articulated, they nonetheless have not put the claimed invention into an allowable condition for reasons set forth below. Referring to the previous Office action, Examiner has cited relevant portions of the references as a means to illustrate the systems as taught by the prior art. As a means of providing further clarification as to what is taught by the references used

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in the first Office action, Examiner has expanded the teachings for comprehensibility while maintaining the same grounds of rejection of the claims, except as noted above in the section labeled "Status of Claims." This information is intended to assist in illuminating the teachings of the references while providing evidence that establishes further support for the rejections of the claims.

9. With respect to the rejection of claim 36 under 35 U.S.C. §101 and further discussed below, Applicant claims that "the Output Expression comprises a representation (thing)...does not render it non-statutory subject matter, unless it does not produce a 'useful, concrete and tangible result'" (Remarks, p.14). Applicant incorrectly states the legal requirements for patentable method claims and appears to confuse the requirements of a "useful, concrete and tangible result" with *the method that produces it*. The expression, whether useful or not, is not what is patentable subject matter. The legal requirements for statutory subject matter insofar as a "useful, concrete and tangible result" are concerned, essentially provide a test as to the patentability of a method or process that produces the result (or expression). For a method or process to be patentable, it must lead to or result in a "useful, concrete and tangible result" (cf *In re Bilski*, USCA 2007-1130 now under appeal to the U.S. Supreme Court). Thus, the language and purpose of the phrase 'useful, concrete and tangible' is part of a series of tests for whether the *method or article of manufacture, etc.* is patentable and does not constitute a foundation for the patentability of the resulting expressions. As previously explained, an expression, as used in the application, is not an apparatus or article of manufacture; nor does it fall within the ambit of any other statutory category under section 101 which provide clear categories of patentable subject matter: "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof ...". Like an abstract idea or equation or formula or law of nature, the mere expression and physical embodiments thereof do not constitute patentable subject matter. The notion of "useful, concrete and tangible result" is thus a test as to whether the methods or processes of the instant application are "new and useful" as methods that do not produce useful results are not patentable. As noted earlier, expressions themselves are amenable to copyright

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protection just as are physically embodied sculptures or paintings. Thus, while a method that produces a useful result may be patentable, the useful result where it is an expression, a rendering, etc. in and of itself is not.

10. In response to Applicant's argument that there is no teaching, suggestion or motivation to combine the references, the Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).
11. To this end, the Examiner recognizes that references cannot be arbitrarily altered or modified and that there must be some reason why one skilled in the art would be motivated to make the proposed modifications. Although the motivation or suggestion to make modifications must be articulated, it is respectfully submitted that there is no requirement that the motivation to make modifications must be expressly articulated within the references themselves. References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures, *In re Bozek*, 163 USPQ 545 (CCPA 1969). Thus, the issue of obviousness is not determined by what the references expressly state but by what they would reasonably suggest to one of ordinary skill in the art, as supported by decisions in *In re Delisle* 406 Fed 1326, 160 USPQ 806; *In re Kell, Terry and Davies* 208 USPQ 871; and *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ 2d 1596, 1598 (Fed. Cir. 1988) (citing *In re Lulu*, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1988)). Moreover, it was determined in *In re Lamberti et al* 192 USPQ 278 (CCPA) that:
- (i) obvious does not require absolute predictability;
 - (ii) non-preferred embodiments of prior art must also be considered; and
 - (iii) the question is not express teaching of references but what they would suggest.
12. According to *In re Jacoby*, 135 USPQ 317 (CCPA 1962), the skilled artisan is presumed to know something more about the art than only what is disclosed in the applied references. Within *In re*

Bode, 193 USPQ 12 (CCPA 1977), every reference relies to some extent on knowledge of persons skilled in the art to complement that which is disclosed therein. In *In re Conrad* 169 USPQ 170 (CCPA), obviousness is not based on express suggestion, but what references taken collectively would suggest.

13. With regard to the limitations of pending claims 1-36, Applicant argues that Examiner incorrectly asserts that "Wong is specifically amenable to 'alternative definitions [that] may also be used.'" (Remarks, p. 15) and that the "membership criteria for inclusion in a cohort as the basis of statistical analyses is old and well-known...." (Remarks, p. 15) and further that the purpose of the Applicant's invention is "not statistical projection" (Remarks, p.16). Applicant's remarks further on the distinctions between the prior art and the application in terms of the empirical identification of opportunities presumably for resource allocation. While Examiner appreciates the purposes for which the application is drawn, it still remains a bit vague as to how the 'identification and targeting of opportunities' leads to improved resource allocation. Examiner understands better the nature of the invention as to how better measures of effectiveness may be assessed and therefore how certain types of interventions can be designed where its effectiveness can be improved. Nevertheless, some clearer and more concrete distinctions between the application and the prior art should be made.
14. Applicant, for example, states that the distinction between McCartney and the instant application stem from the purposes of McCartney which Applicant argues is used for "resource consumption" and that it does not identify a start time and cohort time segment (Remarks, p.18). Applicant further maintains that the notions of "a time window" as taught in Wong compared to the "Cohort time segment" of the Applicant are "profoundly different" (Remarks, p. 18, 22) and, further, that the associated criteria as to whether an entity is included into a cohort is "arbitrarily assigned by the operator" (Remarks, p. 19). This latter however misconstrues how the 'start time' is determined in Wong. Although some aspects of it are determined 'arbitrarily' as in "B can be selected somewhere in between..." (Wong [14,3-4]), other aspects of the time window determination and inclusion in a cohort are based on specified criteria. Specifically, the time point

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A "is defined based on the data extraction protocol... and C is defined by the last day for which the member is still enrolled and eligible for the benefits." (Wong, [14,5]). Moreover, the definition of time point B in Wong is specifically amenable to "alternative definitions [that] may also be used." (Wong [14,16]). Such time windows and time frames are based on information in data files such as "Date of first CHF diagnosis...Date of first CHF hospitalization...Date of first diabetes event..." (Wong [8,51-55]). These are examples of the many types of longitudinal and cohort statistical studies that are based on what are analogous to the instant "cohort time". Indeed, the establishment of relevant time frames based on membership criteria for inclusion in a cohort as the basis of statistical analyses is old and well-known, especially in the medical arts and sciences where the progression of disease, effectiveness of drug regimens and so forth are studied.

15. It is worth pointing out that Applicant acknowledges that the instant application "teaches a central, **non-arbitrary**, starting point (similar to point B in Wong) based on criteria..." (underline Examiner's). This highlights why the teachings of Wong, while not identical to those of the Application render the instant application somewhat obvious. The distinctions thus devolve into using certain types of generated information for some form of regression, prediction analysis or for resource allocation. While the two purposes may seem widely different, they are not necessarily so. Statistical regression analyses are used for a variety of purposes and the novel features of the claimed invention, if any, need to be further embellished and articulated. Applicant is encouraged to contact the Examiner to discuss possible claim amendments to further prosecution.
16. In summary, the Examiner has taken the broadest and most reasonable interpretation of the claim limitations *as written*, in light of the specification. Although the specification may contain recitations of intended use, alternative points of view and subjective interpretative differences between the prior art of record and the present invention as premeditated, it is the claims themselves that are given patentable weight only inasmuch as they are constructed.
17. Regarding claims 34, , Applicant has failed to rebut Examiner's **Official Notices** that
- utilizing computer systems comprising a central processing unit along with system software to

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perform method or algorithmic steps or procedures in data intensive environments,

- employing the use of various types of stratified sampling techniques,

were old and well known in the art at the time of the invention. Examiner notes the following discussion of **Official Notice** taken from the MPEP:

To adequately traverse such a finding, an applicant must specifically point out the supposed errors in the examiner's action, which would include stating why the noticed fact is not considered to be common knowledge or well-known in the art. See 37 CFR 1.111(b). See also *Chevenard*, 139 F.2d at 713, 60 USPQ at 241 ("[I]n the absence of any demand by appellant for the examiner to produce authority for his statement, we will not consider this contention."). A general allegation that the claims define a patentable invention without any reference to the examiner's assertion of official notice would be inadequate. If applicant adequately traverses the examiner's assertion of official notice, the examiner must provide documentary evidence in the next Office action if the rejection is to be maintained. See 37 CFR 1.104(c)(2). See also *Zurko*, 258 F.3d at 1386, 59 USPQ2d at 1697 ("[T]he Board [or examiner] must point to some concrete evidence in the record in support of these findings" to satisfy the substantial evidence test). If the examiner is relying on personal knowledge to support the finding of what is known in the art, the examiner must provide an affidavit or declaration setting forth specific factual statements and explanation to support the finding. See 37 CFR 1.104(d)(2). If applicant does not traverse the examiner's assertion of official notice or applicant's traverse is not adequate, the examiner should clearly indicate in the next Office action that the common knowledge or well-known in the art statement is taken to be admitted prior art because applicant either failed to traverse the examiner's assertion of official notice or that the traverse was inadequate. If the traverse was inadequate, the examiner should include an explanation as to why it was inadequate. (MPEP § 2144.03(C))

Applicant has not "specifically point[ed] out the supposed errors in the examiner's action, which would include stating why the noticed fact is not considered to be common knowledge or well-known in the art." Applicant statements do not amount to a sufficient traversal because no such statements were proffered. For these reasons,

- utilizing computer systems comprising a central processing unit along with system software to perform method or algorithmic steps or procedures in data intensive environments,
 - employing the use of various types of stratified sampling techniques,
- is taken to be admitted prior art.

Claim Objections

18. Claims 1 – 36 are objected to because of the following informalities: The claims variously use acronyms and/or abbreviations and should be replaced by proper expressions. For example, in claim 1, the term UOA-ID should be replaced by "Unit of Analysis-ID (UOA-ID)" and CCT should be replaced by "calendar/clock time (CCT)" so that the general reader, upon reading the claims themselves, can more easily comprehend the meaning of the claims. Appropriate correction is required.
19. Claim 36 also states "having an eligibility criteria" and "from sets of date wherein each individual meets at least one defined criteria..." where the word "criteria" should read "criterion".

Claim Rejections - 35 USC § 112

20. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

21. Claims 1 – 15 and 31 – 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- Claims 1 and 34 recite the phrase "based on their Start Time" and it is unclear what this refers to as it can refer to the Cohort time segments or some attribute of the UOA-ID. Moreover, since the claim language recites "prospective or retrospective Cohort time" the possessive grammar seems inappropriate and is confusing.
 - Claim 31 recites the limitation "analyzing the Output Expression ..." and constitutes post solution human activity and is *prima facie* vague and indefinite as such analysis could refer to any such post solution activity. While the purpose of this limitation appears to narrow the claim by inserting limitations regarding trademark perception, the manner in which this limitation is stated is vague and indefinite. Also, the limitation "identifying a Start Time wherein each UOA-ID ..." is confusing. It appears to imply a constraint satisfaction where the

constraints are the eligibility criteria, but it is unclear from the language whether this should be the minimum time or the maximum time or some time in between. For purposes of examination, Examiner interprets this as meaning the earliest time wherein each UOA-ID satisfies all the criteria.

- Claim 32 recites the limitation "generating an Output Expression showing trends in health care ..." and is *prima facie* vague. What trends does this refer to and how is the generation that shows trends as opposed to other expressions to be generated? In this regard, the application of the method to show trends, at a minimum, fails to indicate several steps that create expressions for showing trends as opposed to other forms of expressions. See MPEP § 2172.01.
- Claim 33 recites the limitation "generating an Output Expression showing trends ... in marketing". This limitation presents the same problems and issues as stated above for claim 32.
- Claim 35 recites the limitation "said method is used for applications selected ... trademarks applications, and health care applications". This limitation presents the same problems and issues as stated above for claims 31 – 33.
- Claim 36 recites the phrase "from sets of date wherein each individual unit meet..." and is confusing. Does this mean individual meet or does it mean individuals satisfy some criterion? While Examiner believes that later meaning is the intended meaning, the phrasing is confusing and should be revised. Also, "sets of date" is confusing.

Claim Rejections - 35 USC § 101

22. 35 U.S.C. §101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

23. Claims 1 – 36 are rejected under 35 U.S.C. §101 because the claimed invention is directed to non-statutory subject matter. Based on Supreme Court precedent, and recent Federal Circuit

decisions, the Office's guidance to examiners is that a §101 process must (1) be tied to another statutory class (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or materials) to a different state or thing. *Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *Cochrane v. Deener*, 94 U.S. 780,787-88 (1876). An example of a method claim that would not qualify as a statutory process would be a claim that recited purely mental steps. Thus, to qualify as a §101 statutory process, the claim should positively recite the other statutory class (the thing or product) to which it is tied, for example by identifying the apparatus that accomplishes the method steps, or positively recite the subject matter that is being transformed, for example by identifying the material that is being changed to a different state.

24. Examiner notes that while these claims do recite some components of the elements of another statutory class, they are insufficient to substantively tie them to another statutory class in that no correspondence is discernable between the various method steps and the particular components of the computer system. Nominal recitations of structure in an otherwise ineligible method fail to make the method a statutory process. See *Benson*, 409 U.S. at 71-72. As *Comiskey* recognized, "the mere use of the machine to collect data necessary for application of the mental process may not make the claim patentable subject matter." *Comiskey*, 499 F.3d at 1380 (citing *In re Grams*, 888 F.2d 835, 839-40 (Fed. Cir.1989)). Incidental physical limitations, such as data gathering, field of use limitations, and post-solution activity are not enough to convert an abstract idea into a statutory process. In other words, nominal or token recitations of structure in a method claim do not convert an otherwise ineligible claim into an eligible one. Further, it is noted that the fact that the method is computer implemented has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

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25. With respect to claim 36, the claim refers to an expression for which patent protection is sought which may not necessarily take the form of a tangible or concrete result, but could merely be displayed or even verbally communicated. As stated above, expressions, physically embodied or not do not constitute "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof ..." Therefore, expressions, as noted above, are not amenable to patent protection under this statute.
26. As a matter of general guidance concerning use of method claims, language using "a computer-executable program tangibly embodied on a computer readable medium" is a suggestion for how to bring such claims into compliance with 35 U.S.C. §101 because "a computer-executable program tangibly embodied on a computer readable medium" is statutory subject matter.

Claim Rejections - 35 USC § 103

27. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

28. Claims 1 - 5, 9, 11 - 20, 23, 25 - 28 and 30 - 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCartney (PG-Pub 2003/0065534 A1) in view of Wong (US 5,976,082 A).

Claims 1 and 34:

McCartney, as shown, discloses and/or describes the following limitations:

- *A method of improving resource allocation* (McCartney [0002]: "...and allows for optimized allocation of health care resources.") *comprising the steps of:*
 - *identifying at least one criterion;*
 - *identifying sets of information wherein each set of information includes*

- a UOA-ID (Applicant on page 9, line 22: *...means the particular individual UOA entity involved in the study* and further provides examples on page 10, line 2 as *patients having a common diagnosis or condition...* McCartney [0039] also describes a Patient Group: "...for example all patients who had a simple appendectomy are in a Patient Group."),
- a CCT (Applicant on page 9, line 17 refers to *calendar clock date/time*. McCartney [0003] refers to dynamic periods of time for given situations: "For example a person admitted to a hospital [] will generally require operating room time, recovery ward time..." (emphasis added) and further describes in [0004] patients that must be "tracked virtually on a real time basis" (emphasis added)) and a
- VAR Value (Applicant on page 10, line 21 defines VAR. McCartney, in at least [0064-5] also refers to various values associated with resource allocation decisions and modules that determine them: "generating the case cost profile rather than the adjusted values.");
- grouping each UOA-ID into an appropriate Type (Applicant defines Type on page 10, line 8. McCartney in at least [0026] describes this same limitation: "the grouping systems in different countries generally use the same approach to grouping disease and treatment case types." Emphasis added.);

McCartney does not specifically include the following limitations, but Wong, as shown does.

- identifying a Start Time wherein each UOA-ID has met said at least one criterion; (Applicant defines the *start time* generally as the time at which group membership criteria are satisfied. Wong, in at least [0050] states: "First available date of enrollment (i.e., start of dataset or enrollment date) [] Date of first CHF diagnosis (ICD-9 code in any position)...");
- forming at least one prospective or retrospective Cohort time segment for each UOA-ID based on their Start Time (Wong, in at least the abstract states: "A time window is

defined to provide a timeframe from which to judge whether events should be considered in subsequent processing..." where 'time window' is equivalent to a *Cohort time segment*. Also, Wong [0013] relates such time windows to a specified plurality of variables to identify analysis and prediction regions. Thus, such time segments entertain those "risk groups" or other specified criteria.);

- *placing the UOA-ID into the appropriate time segment* (Wong in at least [0013] states: "...the time window is used to identify an analysis region..." and in [0017] "...using the **time window** and the set of variables, to generate an **analysis file**..." The method of 'using the time window' is thus equivalent to the limitation in that the set of variables is associated with the particular time window. This association corresponds to the relevant *UOA-ID* that is associated with *the appropriate time segment*);
- *calculating an eligibility score for each UOA-ID for each time segment* (Applicant refers to *eligibility score* on page 14, line 17 as corresponding to the time-frame in which a unit of analysis is available for study both 'prospectively and retrospectively' and further provides an example where the score is given in terms of months. Wong, in at least [0161] describes the use of analysis weights associated with time windows: "...analysis weights which reflect proximity to the event to be predicted can be used, for example, within 3 months \times 1, 3-6 months \times 0.75 ...");

McCartney, as shown, discloses and/or describes the following limitations:

- *calculating an Eligible Adjusted Variable Value* (McCartney, in at least [0064-5] states: "...to reconcile [] case costing data available [], resulting in adjusted cost ..." (emphasis added) where adjusted cost corresponds to *Adjusted Variable Value*.);
and
- *generating at least one Output Expression* (McCartney, in at least [0171] states: "The output generated by applying the model is a file containing a list of all of the CHF patients ordered by an indicator representative of the likelihood that that patient will

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have an adverse health outcome (i.e., experience that defined by the dependent variable). This list can then be divided into subgroups such as in 5% or 10% increments of patients likely to have the adverse health outcome..." (emphasis added) wherein the various groups corresponds to *eligible* data entities.)

With respect to claim 34, Examiner takes **as admitted prior art** that it is old and well-known as well as commonplace in the technical and medical arts to utilize computer systems comprising a central processing unit along with system software to perform method or algorithmic steps or procedures in data intensive environments. Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention to combine the resource allocation method of McCartney with Wong's recitation of time-dependent variables because each pertain to the statistical analysis of health care systems and disease management issues and seek to identify ways to improve the efficiency of healthcare delivery systems.

Claims 2 and 17:

McCartney/Wong disclose the limitations as shown in the rejections of claims 1 and 16 above.

McCartney as shown, further discloses and/or describes the following limitations:

- *The method of claim 1 further comprising the step of transforming the Output Expressions from being expressed in Cohort time segments...* (McCartney, in at least [0003], describes various types of *cohort time*: "They will generally require operating room **time**, recovery ward **time**...")

McCartney does not specifically include the following limitations, but Wong, as shown does.

...to being expressed in CCT segments (Wong, in at least claim 1, states a step which includes: "converting data representing the extracted claims information and the defined events into files containing event level information". This conversion process is equivalent to a transformation of *cohort time segments* to *CCT segments* because CCT segments pertain to the times at which events occur. Moreover, in at least [0048] specifically states "the information is converted into an event level format." Finally, in [0051], Wong states: "Primary data file 2 is an events level file with a record for each event ordered by member and the chronological date of the event, in the present invention, presented in descending order of event date," (emphasis added).)

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the statistical methods of McCartney and Wong because translating time periods associated with conditions to absolute or calendar time facilitates the ability of analysts to make meaningful assessments of resource utilization and discern trends in the data.

Claims 3 and 18:

McCartney/Wong disclose the limitations as shown in the rejections of claim 1 above and 16 below. McCartney/Wong do not specifically disclose *wherein said method is performed using a system comprising a central processing unit for implementing system software effective for performing the method*. However, Examiner takes **as admitted prior art** that it is old and well-known as well as commonplace in the technical and medical arts to utilize computer systems comprising a central processing unit along with system software to perform method or algorithmic steps or procedures in data intensive environments. Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention to utilize a central processing unit along with system software because their use enables the practical utility by increasing the efficiency and reliability of the resource allocation system.

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Claims 4, 5, 9 and 19–25, 35:

McCartney/Wong disclose the limitations as shown in the rejections of claim 1 (above), 16 (below) and 34 (above). The limitations in these claims recite intended use and so are not given patentable weight.

Claims 11 and 26:

McCartney/Wong disclose and/or describe the limitations of claim 1 and 16 above. McCartney further discloses and/or describes the following limitations:

- *The method of claim 1 wherein each Output Expression is generated by the method comprising the step of calculating an EAV based on a summary metric for each UOA-ID per Type* (McCartney, in at least [0064-5] states: "...to reconcile [] case costing data available [], resulting in adjusted cost ..." (emphasis added) where adjusted cost corresponds to *Adjusted Variable Value*. McCartney, in at least [0070] states: "For each of the Patient Groups [... a column] [] that identifies the average length of stay (ALOS) associated per case per Patient Group." (emphasis added) where the 'average length...' corresponds to a *summary metric* for which a value is associated.)

Claims 12 and 27:

McCartney/Wong disclose and/or describe the limitations of claim 1 above and 16 below. Wong further discloses and/or describes the following limitations:

- *determining a DV per Type per time segment* (See Wong, in at least [0150]: "...this is a dichotomous variable..." (emphasis added) See also the rejection of claim 1 above and **admitted prior art** below);
- *calculating an EAV summary metric for all UOA-IDs per Type per time segment* (See the rejections of claim 11 above); *and*
- *calculating an EAV Net Value per Type per time segment* (See the rejections of claims 1 above. McCartney also specifically refers to 'total' resource use. For example, in at least [0005]: "[R]esearch has indicated that while length of stay can be a useful indicator of total resource use, it can be a misleading indicator for some case

types and some resources." and in [0057] "total consumption information" and in [0063] "actual total statistical unit usage..." (emphasis added) and thus corresponds to a Net Value per Type.)

McCartney/Wong do not specifically describe the limitations regarding a DV per time segment, but, 'DV', being a 'dichotomous variable' (see page 27, lines 15-17) is simply a Boolean value that is used to stratify the data. Examiner's takes **as admitted prior art** that it is well known and commonplace in the statistical analysis arts to employ the use of various types of stratified sampling techniques. These strata are, by definition, mutually exclusive. Applicant employs the term 'DV' to define two mutually exclusive sets of values depending on the context which, in Wong, also involves a time-based aspect (see Wong in at least [0150]: "Resources counted from time of cost..."). Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention to use a Boolean technique for stratifying data in conjunction with the health care and disease management methods of McCartney and Wong because many types of data must be either included in an output analysis or excluded from it in order to make the analysis meaningful.

Claims 13 and 28:

McCartney/Wong disclose and/or describe the limitations of claims 1 above and 16 below.

McCartney/Wong, as shown, further discloses and/or describes the following limitations:

- *determining a RORA* (Wong, in at least [0150] wherein "resource utilization is measured in dollars." 'Resource utilization' is thus equivalent to *return on resource allocation*' (RORA));
- *determining an Outcome* (McCartney, in at least [0171] states: "The output generated by applying the model is a file [...]" (emphasis added) where the 'output generated' corresponds to *determining an Outcome*.);
- *calculating a NNT* (Wong, in at least [0002] describes his invention in terms of "targeted interventions" relative to congestive heart failure patients and thus requires the determination of the *number needed to target (NNT)*.)

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- *calculating an EAV Net Value per Type per time segment* (See the rejection of claim 1 relative to the EAV calculation. Also, McCartney also specifically refers to 'total' resource use. For example, in at least [0005]: "[R]esearch has indicated that while length of stay can be a useful indicator of total resource use, it can be a misleading indicator for some case types and some resources." and in [0057] "total consumption information" and in [0063] "actual total statistical unit usage..." (emphasis added) and thus corresponds to a Net Value per Type.); and
- *calculating the maximum available RA per UOA-ID per time segment* (See the rejection of the limitation above regarding RORA. Note, that McCartney, in at least [0053], refers to "relative resource weightings" in which it is fairly implied that a weighting of 1 corresponds to the maximum weight, hence corresponds to the instant limitation.)

Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention to combine the resource allocation method of McCartney with Wong's recitation of time-dependent variables because each pertain to the statistical analysis of health care systems and disease management issues and seek to identify ways to improve the efficiency of healthcare delivery systems.

Claims 14 and 29:

McCartney/Wong disclose and/or describe the limitations of claim 1 above and 16 below.

McCartney/Wong, as shown, further discloses and/or describes the following limitations:

- *determining a RA* (See the rejection of claim 13. Note, that McCartney, in at least [0053], refers to "relative resource weightings" in which it is fairly implied that a weighting of 1 corresponds to the maximum weight, hence corresponds to the instant limitation.);
- *determining an Outcome* (McCartney, in at least [0171] states: "The output generated by applying the model is a file [...]" (emphasis added) where the 'output generated' corresponds to *determining an Outcome*.);

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- *calculating a NNT* (Wong, in at least [0002] describes his invention in terms of "targeted interventions" relative to congestive heart failure patients and thus requires the determination of the *number needed to target (NNT)*.);
- *calculating an EAV Net Value per Type per time segment* (Also, McCartney also specifically refers to 'total' resource use. For example, in at least [0005]: "[R]esearch has indicated that while length of stay can be a useful indicator of total resource use, it can be a misleading indicator for some case types and some resources." and in [0057] "total consumption information" and in [0063] "actual total statistical unit usage..." (emphasis added) and thus corresponds to a Net Value per Type.); and
- *calculating the RORA per UOA-ID per time segment* (See the rejection of claim 8. Note that claim 13 refers to *determining a RORA* whereas here, this calculation is based on stratified data. However, other limitation in claim 13 effectively addresses this stratification).

Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention to combine the resource allocation method of McCartney with Wong's recitation of time-dependent variables because each pertain to the statistical analysis of health care systems and disease management issues and seek to identify ways to improve the efficiency of healthcare delivery systems.

Claims 15 and 30:

McCartney/Wong disclose and/or describe the limitations of claim 1 and 16 above.

McCartney/Wong, as shown, discloses and/or describes the following limitations:

- *determining a RORA* (Wong, in at least [0150] wherein "resource utilization is measured in dollars." 'Resource utilization' is thus equivalent to *return on resource allocation*' (RORA));
- *determining a RA* (McCartney, in at least [0053], refers to "relative resource weightings" in which it is fairly implied that a weighting of 1 corresponds to the maximum weight, hence corresponds to the instant limitation.);

- *calculating a NNT* (Wong, in at least [0002] describes his invention in terms of "targeted interventions" relative to congestive heart failure patients and thus requires the determination of the *number needed to target (NNT)*.);
- *calculating an EAV Net Value per Type per time segment* (McCartney, in at least [0064-5] states: "...to reconcile [] case costing data available [], resulting in adjusted cost ..." (emphasis added) where adjusted cost corresponds to *Adjusted Variable Value*. Also, McCartney also specifically refers to 'total' resource use. For example, in at least [0005]: "[R]esearch has indicated that while length of stay can be a useful indicator of total resource use, it can be a misleading indicator for some case types and some resources." and in [0057] "total consumption information" and in [0063] "actual total statistical unit usage..." (emphasis added) and thus corresponds to a *Net Value per Type*.); and
- *calculating an Output per UOA-ID per time segment* (McCartney, in at least [0171] states: "The output generated by applying the model is a file containing a list of all of the CHF patients ordered by an indicator representative of the likelihood that that patient will have an adverse health outcome (i.e., experience that defined by the dependent variable). This list can then be divided into subgroups such as in 5% or 10% increments of patients likely to have the adverse health outcome..." (emphasis added). Wong, in at least [0161] describes the use of analysis weights associated with time windows: "...analysis weights which reflect proximity to the event to be predicted can be used, for example, within 3 months \times 1, 3-6 months \times 0.75 ...").

Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention to combine the methods of McCartney with the invention of Wong because they pertain to the statistical analysis of health care systems and disease management issues and seek to identify ways to improve the efficiency of healthcare delivery systems.

Claim 16:

McCartney, as shown, discloses and/or describes the following limitations:

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- *A method for improving resource allocation using a plurality of sets of information*
(See the preamble to the rejection of claim 1. Note also that *plurality of sets* is equivalent to *identifying sets of information* as in claim 1), *the method comprising the steps of:*
 - *for each set of information, identifying*
 - *an UOA-ID* (See the rejection of claim 1),
 - *a Type* (McCartney, in at least [0026] describes a “classification system” where elements of defined groups must meet certain criteria for inclusion in the relevant group.),
 - *a CCT* (See the rejection of claim 1) *and*
 - *a VAR Value* (See the rejection of claim 1);
 - *grouping each UOA-ID into an appropriate Grouper* (McCartney in at least [0030] refers to examples of groups and subgroups of patients. In [0026] McCartney specifically refers to “grouping systems” and thus corresponds to a *Grouper*.);
 - *placing each AdjVAR Value into the appropriate time segment* (McCartney in at least [0009] states: “a health care resource profiling system that includes a [] database [] quantifying a total use of a health care resource [] during a predefined time period...” where the notion of ‘predefined’ circumscribes time segments, and *ipso facto* an appropriate time segment.);
 - *calculating an eligibility score for each UOA-ID* (See the rejection of claim 1); *and*
 - *generating an Output Expression* (See the rejection of claim 1).

McCartney does not specifically include the following limitations, but Wong, as shown does.

- *identifying a Start Time wherein said Start time is the earliest CCT for each specific UOA-ID per Type* (See the rejection of claim 1. Wong [0156] also refers to a time window that starts at some particular point and in [0050] refers to the “First available date of enrollment (i.e., start of dataset or enrollment date)” which, in effect corresponds to the start time for a particular group or class of patients.);

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- *identifying a time segment duration* (Wong in at least [0167] refers to "length of stay");
- *forming time segments based on the Start Time wherein each UOA-ID meet a certain eligibility criteria* (Wong in at least [0017] describes the acts of : "defining a time window for providing a timeframe" where 'defining' is equivalent to *forming*... Wong [0050] states: "First available date of enrollment (i.e., start of dataset or enrollment date) [] Date of first CHF diagnosis (ICD-9 code in any position)..." which corresponds to such eligibility criteria.);
- *adjusting and standardizing each VAR Value to create AdjVAR Values* (See the rejection in claim 1 of the limitation component *VAR Value* that specifically mentions "adjusted values");

Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention to combine the resource allocation method of McCartney with Wong's recitation of time-dependent variables because each pertain to the statistical analysis of health care systems and disease management issues and seek to identify ways to improve the efficiency of healthcare delivery systems.

Claims 31, 32 and 33:

McCartney, as shown, discloses and/or describes the following limitations:

- *identifying at least one set of information each set comprising*
 - *a UOA, and a UOA-ID* (Applicant on page 9, line 22: "...means the particular individual UOA entity involved in the study and further provides examples on page 10, line 2 as *patients having a common diagnosis or condition*... McCartney [0039] also describes a Patient Group: "...for example all patients who had a simple appendectomy are in a Patient Group."),
 - *a Type* (McCartney, in at least [0026] describes a "classification system" where elements of defined groups must meet certain criteria for inclusion in the relevant group.),

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- *a CCT* (Applicant on page 9, line 17 refers to *calendar clock date/time*. McCartney [0003] refers to dynamic periods of time for given situations: "For example a person admitted to a hospital [] will generally require operating room time, recovery ward time..." (emphasis added) and further describes in [0004] patients that must be "tracked virtually on a real time basis"), *and*
- *and a VAR Value* (Applicant on page 10, line 21 defines VAR. McCartney, in at least [0064-5] also refers to various values associated with resource allocation decisions and modules that determine them: "generating the case cost profile rather than the adjusted values.");
- *grouping each UOA-ID into an appropriate Type* (Applicant defines *Type* on page 10, line 8. McCartney in at least [0026] describes this same limitation: "the grouping systems in different countries generally use the same approach to grouping disease and treatment case types." Emphasis added.);
- *placing the VAR Value into the appropriate time segment* (McCartney in at least [0009] states: "a health care resource profiling system that includes a [] database [] quantifying a total use of a health care resource [] during a predefined time period..." where the notion of 'predefined' circumscribes time segments, and *ipso facto* an appropriate time segment.);
- *calculating an Eligible Adjusted Variable Value* (McCartney, in at least [0064-5] states: "...to reconcile [] case costing data available [], resulting in adjusted cost ..." (emphasis added) where adjusted cost corresponds to *Adjusted Variable Value*.);
- *and generating Output Expression* (McCartney, in at least [0171] states: "The output generated by applying the model is a file containing a list of all of the CHF patients ordered by an indicator representative of the likelihood that that patient will have an adverse health outcome (i.e., experience that defined by the dependent variable).
- The last limitations in each of these claims recite intended use and so are not given patentable weight.

McCartney does not specifically include the following limitations, but Wong, as shown does.

- *identifying a Start Time wherein each UOA-ID meets all of the eligibility criteria to be included into a Population* (Applicant defines the *start time* generally as the time at which group membership criteria are satisfied. Wong, in at least [0050] states: "First available date of enrollment (i.e., start of dataset or enrollment date) [] Date of first CHF diagnosis (ICD-9 code in any position)...");
- *forming at least one Cohort Time segment based on the Start Time* (Wong, in at least the abstract states: "A time window is defined to provide a timeframe from which to judge whether events should be considered in subsequent processing..." where 'time window' is equivalent to a *Cohort time segment*.);
- *calculating an eligibility score for each UOA-ID for each time segment* (Applicant refers to *eligibility score* on page 14, line 17 as corresponding to the time-frame in which a unit of analysis is available for study both 'prospectively and retrospectively' and further provides an example where the score is given in terms of months. Wong, in at least [0161] describes the use of analysis weights associated with time windows: "...analysis weights which reflect proximity to the event to be predicted can be used, for example, within 3 months \times 1, 3-6 months \times 0.75 ...");

Therefore, it would have been obvious to one with ordinary skill in the art at the time of the invention to combine the resource allocation method of McCartney with Wong's recitation of time-dependent variables because each pertain to the statistical analysis of health care systems and disease management issues and seek to identify ways to improve the efficiency of healthcare delivery systems.

Claim 36:

McCartney, as shown, discloses and/or describes the following limitations:

An Output Expression comprising a representation showing EAV trends of a particular Population [...], said trends are expressed in Cohort time segments [...] (Applicant on page 17, line 14 states that EAV may be, but are not limited to, a quantity count, dollar value, number of products, and

number of events, etc. hence, correspond to a value of interest expressed in *Cohort time segments*. But a *cohort time segment* is the time segment a particular entity (unit of analysis) satisfies a given criterion. McCartney, in at least [0004] describes the burden of "track[ing] every resource that is used in respect of every patients by predetermined case types [] during the time that the patient is in the care of the health care provider." Thus, 'predetermined case types' associated with certain defined time periods corresponds to *cohort time segments* and the notion of tracking resources used is a form of *showing EAV trends*. Also, McCartney, in at least [0003] describes values and costs which correspond to *EAV* and describes trends which correspond to *cohort time trends*).

McCartney does not specifically teach that a particular population *having an eligibility criteria and formed from individual units each meeting at least one defined criteria*, and where the cohort time segments are *based on a Start Time wherein each individual unit meets all of the eligibility criteria to be included into the Population; a showing NNT trends of a particular Population; said trends are expressed in Cohort time segments.*, but Wong does and in at least [0050] states: "First available date of enrollment (i.e., start of dataset or enrollment date) [] Date of first CHF diagnosis (ICD-9 code in any position)..." which corresponds to such eligibility criteria. Wong [abstract] further refers to cohort time segments where individuals meet such eligibility criteria: "A time window is defined to ... judge whether events should be considered...", hence indicates some criteria for judging whether information is proper for analysis, i.e., eligible. Wong further describes the 'number needed to target' in [0002] regarding "targeted interventions" relative to congestive heart failure patients. Wong, in at least claim 1, states a step which includes: "converting data representing the extracted claims information and the defined events into files containing event level information". This conversion process is equivalent to a transformation of *cohort time segments* to *CCT segments* because CCT segments pertain to the times at which events occur. Moreover, in at least [0048] Wong specifically states "the information is converted into an event level format." Finally, in [0051], Wong states: "Primary data file 2 is an events level file with a record for each event ordered by member and the chronological date of the event, in

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the present invention, presented in descending order of event date." (emphasis added). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the statistical methods of McCartney and Wong because translating time periods associated with conditions to absolute or calendar time facilitates the ability of analysts to make meaningful assessments of resource utilization and discern trends in the data.

Conclusion

Any inquiry of a general nature or relating to the status of this application or concerning this communication or earlier communications from the Examiner should be directed to **Mark A. Fleischer** whose telephone number is **571.270.3925**. The Examiner can normally be reached on Monday-Friday, 9:30am-5:00pm. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, **Bradley Bayat** whose telephone number is **571.272.6704** may be contacted.

The prior art made of record and not relied upon that is considered pertinent to applicant's disclosure are:

- Schloss, *et al.* (US 5692125 A) describes and/or discloses a system and methods to analyze resource allocation decisions where there are fixed and dynamic conditions.
- Geskus, R. "Methods for estimating the AIDS incubation time distribution when date of seroconversion is censored" (2001) describes use of cohort studies with respect to time-based events.
- Gordin, Fred, *et al.* "Early Manifestations of Disseminated Mycobacterium avium Complex Disease: A Prospective Evaluation" also describes use of cohort studies with respect to time-based events.
- Goggins, William, *et al.* "Applying The Cox Proportional Hazards Model For Analysis Of Latency Data With Interval Censoring" also describes use of cohort studies with respect to time-based events.
- Kim, S. *et al.* "Strategies for Cohort Sampling Under the Cox Proportional Hazards Model, Application to an AIDS Clinical Trial" also describes use of cohort studies with respect to time-based events.
- Seare, et al. (US 6223164 B1)

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22 June 2009

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